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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,762	09/08/2003	Gloria Cristalli	02-166	3962

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CV THERAPEUTICS, INC.
3172 PORTER DRIVE
PALO ALTO, CA 94304

EXAMINER	
CRANE, LAWRENCE E	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,762	CRISTALLI, GLORIA	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 6, 2004 (IDS)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-8,11,12,14,18-23 and 27* is/are allowed.

6)☒ Claim(s) *13,16 and 28-31* is/are rejected.

7)☒ Claim(s) *9,10,15 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/06/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Abstract of the Disclosure is objected to because is does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

Applicant is respectfully requested to include a generic structure to illustrate the particular genus of A_3 agonists being claimed.

No claims have been cancelled, no claims have been amended, the disclosure has not been amended, and no new claims have been added as of the date of this Office action. An Information Disclosure Statement (IDS) filed July 6, 2004 has been received with all cited references and made of record.

Claims **1-31** remain in the case.

The disclosure is objected to because of the following informalities:

At page 7, line 25, the term "cycloaklyl" is a misspelling of -- cycloalkyl --. Applicant is respectfully requested to recheck the spelling of technical terms in the disclosure.

Appropriate correction is required.

Claims **24-25** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention; the scope is excessive in view of the disclosed exemplifications.

The definitions of medicinal applications in claims **24 and 25** are directed to a vast number of disease conditions the treatments of which have not been described in the instant disclosure in a manner permitting the ordinary practitioner to have the guidance necessary to use (administer) any of the compounds encompassed by the noted claims as active ingredients. Examiner finds only disclosures of adenosine A_3 receptor binding constants provided in the "Examples" section, a showing which fails to provide an adequate basis for the scope of medicinal applications implied by the term "cancer," a generic term which covers a truly vast array of different disease conditions with substantial variations in etiologies. The same criticism applies to the term "method of treating a disease state by stimulating adenosine A_3 receptors."

Claims **24-26** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims, as specified in claim **24**, extends to all disease conditions wherein stimulation of the adenosine A_3 receptor is implicated in an effective treatment, but the particular disease conditions to be treated has not been specified. In addition, in claim **25**, the term "cancer" is also generic to a very large array of disease conditions none of which have been specified in any other claim.

B. The nature of the invention is directed to the treatment of all disease conditions wherein a compound of claim **1** is administered to cause stimulation of the adenosine A_3 receptor in an effective treatment of a disease condition.

C. The state of the prior art as represented by the art presently of record is very limited in scope and therefore does not provide adequate support for the breadth of the instant claims.

D. The level of one or ordinary skill is high because the compounds of record represent minor variations of compounds known in the art. Additionally, the administration of similar compounds to cause pharmacologically effects by stimulation of various adenosine receptors is also well known in the art.

E. The level of predictability in the art is low because the administration of compounds alleged to be capable of adenosine A_3 receptor stimulation to treat any specific disease conditions including cancer or neutropenia is not known in the art.

F. The amount of direction provided by the inventor is limited to disclosure of how to make the instant claimed compounds and that said compounds are capable of binding to the A_3 receptor. The is no showing to support claim **25** which asserts the instant disclosed compounds

are effective in the treatment of any "cancer" or any other particular disease condition wherein stimulation of the adenosine A_3 receptor is implicated in an effective treatment.

G. The existence of working examples is limited to synthetic examples and to disclosure of the adenosine A_3 receptor binding constants for several compounds of claim **1**.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive because the instant disclosure fails to provide an adequate showing that the compounds of claim **1** are effective in the treatment of any particular disease conditions, either by a showing of *in vitro* or *in vivo* administration to any host in need thereof to treat any disease condition whatsoever.

Claim **13** is rejected under 35 U.S.C. §112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

The compound named in claim **13** fails to further limit the subject matter of claim **1** because the necessary substitution of N^6 is absent, i.e. has not been defined. Therefore, the subject matter of claim **13** is not included within the scope of independent claim **1**.

Claims **9, 10 and 15-17** are objected to because of the following informalities:

In claim **9** at line 2, the term "methoxyamino2" is an incorrect term for a chemical name. Appropriate clarification is respectfully requested.

In claims **10 and 17** at line 2, the term "ethynl" included within the chemical name is incorrect. Did applicant intend the term to read -- ethynyl --? Also in claim **10** at line 2, see also the term "lphenyl" which appears to be a misspelling of -- phenyl --.

In claim **16** at line 2, the term " 5-hydroxymethyl " appears to have been repeated later in the chemical name, suggesting an unnecessary duplication. Applicant is respectfully requested to review the name to insure that all the necessary component parts have been included in the name. See also claim **15** for the same error.

Appropriate correction is required.

Claims **13, 16 and 28-31** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim **13** is incomplete because the "purinyl" component has not been included within the chemical name. Appropriate correction is respectfully requested.

In claim **16** at line 2, the term " -ynyl" appears to be incomplete because the immediately preceding term "cyclohexyl" cannot include a triple bond within its structure. Applicant is respectfully requested to review the name to insure that all the necessary component parts have been included in the name.

In claim **28** the proposed chemical process step will not produce the proposed transformation because the C-6 substituent is already present, and because the C-2 replacement requires a transition metal complex and an acetylenic co-reactant neither of which have been specified.

Claims **13, 16, 24-26 and 28-31** would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112.

Claims **9, 10, 15 and 17** are objected for the reasons noted above, but would be allowable if rewritten to overcome the bases for the objections.

Presently claims **1-8, 11-12, 14, 18-23 and 27** appear to be allowable as submitted assuming that the objections noted above have been effectively addressed by amendment.

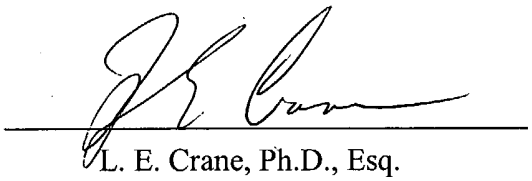
Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 703-872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at **571-272-0661**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec
09/29/2004



L. E. Crane, Ph.D., Esq.
Primary Patent Examiner
Technology Center 1600